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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,228	11/16/2005	Graham McIntyre	15373.0002	6730

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/526,228	**Applicant(s)** MCINTYRE ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18December2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): see attached Detailed Action.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *3,8-10,12-26*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 18 December 2007, is acknowledged. Claims 1, 2 have been cancelled. Claims 3, 8, 9, 12, 15, 17, 18, and 19 have been amended.

Although the submission resulted in new rejections necessitated by amendment (see the following), the amended claims have been entered and considered in order to further prosecution of the claims.

2. Claims 3, 8-10, and 12-26 are pending and under consideration.

Rejections Moot/Withdrawn

3. The rejection of claims 1 and 2 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is moot in light of the cancelation of the claims.

4. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310), is moot in light of the cancelation of the claims.

5. The rejection of claim 13 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn.

6. The rejection of claims 18-25 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

Rejections Maintained

7. The rejection of claims 3, 8-10, 12, 14-17 and 26, under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is maintained for reasons of record.

Applicants argue that the amendment of claim 3 to require a pharmaceutically acceptable carrier no longer reads on a product of nature.

The examiner has considered applicants' argument, but does not find it persuasive.

Currently amended claim 3 recites "A pharmaceutical composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*, and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modiefies a cellular immune response."

The use of the term "composition comprising" allows for the presence of both living and dead whole cells, which would read on a product of nature which would contain both living and dead whole cells. Various *Rhodococcus* bacteria,for example, has been found in aquatic habitats, i.e., water (Bergey's Manual of Systemic Bacteriology, Vol. 2, pages 1472-1481). Water is a pharmaceutically acceptable carrier. Thus, the bacteria in water, i.e., a product of nature, fulfills the requirements of claims 3, 15, 16, and 17.

Claims 8-10 are directed to the composition according to claim 3 "for use as" a medicament or vaccine. The recitation of "for use as" is merely an intended use and as such places not patentable criterion on the composition claimed.

Claim 12 is directed to the composition of claim 3, further comprising "an antigen". Since no further restriction is placed upon the term "antigen", the source of the antigen can be the bacteria. Thus, the composition remains reading on a product of nature.

Claim 14 is directed to the composition of claim 3, further comprising two or more "antigens". Since no further restriction is placed upon the term "antigen", the source of the antigen can be the bacteria. Thus, the composition remains reading on a product of nature.

8. The rejection of claims 3 and 8-10 under 35 U.S.C. 102(b) as being anticipated by Matson et al (U.S. Pat. No. 4,599,310), is

Applicants' argue that Matson et al do not describe a pharmaceutical composition that includes 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*, and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modiefies a cellular immune response nor administration of bacterial cells to patients.

The examiner has considered applicants' argument, but does not find it persuasive for reasons of record.

Currently amended claim 3 recites "A pharmaceutical composition comprising 10^4 to 10^{10} killed whole cells of a bacterium selected from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides*, and a pharmaceutically acceptable carrier, diluent or excipient, which pharmaceutical composition in use modiefies a cellular immune response." Claims 8-10 are directed to the composition according to claim 3 "for use as" a medicament or vaccine. The recitation of "for use as" is merely an intended use and as such places not patentable criterion on the composition claimed.

Matson et al do teach a composition comprising a bacterium selected from the genera *Rhodococcus* in a medium containing an assimilable carbon source such as glucose, thus, reading on the bacteria in injectable glucose water. In the absence of evidence to the contrary, the compositions contain live and dead (10^4 to 10^{10}) whole bacteria.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Previously presented claims 18 and 19 are drawn to a method for immunizing a subject comprising administering a pharmaceutical composition and/or immune modulator composition according to any one of claim 1-3, wherein claim 2 defined the immune modulator composition as comprising an antigen and an adjuvant, wherein "said adjuvant" comprised a whole cell of a bacterium from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides.*

However, in newly amended claims 18 and 19, the immune modulator composition appears to be defined differently, i.e., no longer comprising an adjuvant, but remaining to be described as comprising a whole cell of a bacterium from the genera *Rhodococcus, Gordonia, Dietzia, Tsukamurella,* and *Nocardioides.* It is therefore unclear what new definition of "immune modulator composition" is to be applied.

11. Newly amended claims 8-10, 12-17, and 26 are rejected under 35 U.S.C. 112, second paragraph, for insufficient antecedent basis.

The claims recite the limitation "An immune modulator composition or a pharmaceutical composition according to claim 3". There is insufficient antecedent basis for this limitation in the claims because claim 3 is only drawn to a pharmaceutical composition.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

January 14, 2008